UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION and THE PEOPLE OF THE STATE OF NEW YORK, by LETITIA JAMES, Attorney General of the State of New York,

Plaintiffs,

v.

QUINCY BIOSCIENCE HOLDING COMPANY, INC., a corporation; QUINCY BIOSCIENCE, LLC, a limited liability company; PREVAGEN, INC., a corporation d/b/a/ SUGAR RIVER SUPPLEMENTS; QUINCY BIOSCIENCE MANUFACTURING, LLC, a limited liability company; and MARK UNDERWOOD, individually and as an officer of QUINCY BIOSCIENCE HOLDING COMPANY, INC., QUINCY BIOSCIENCE, LLC, and PREVAGEN, INC.,

Defendants.

Case No. 1:17-cv-00124-LLS

PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION TO EXCLUDE THE TESTIMONY OF DRS. DAVID SCHWARTZ, DAVID KATZ, LEE-JEN WEI, MINDY KURZER, RICHARD GOODMAN, AND DAVID GORTLER

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Plaintiffs, the Federal Trade Commission and the People of the State of New York by Letitia James, Attorney General of the State of New York, respectfully submit this Reply in support of their Motion to Exclude the Testimony of Drs. David Schwartz, David Katz, Lee-Jen Wei, Mindy Kurzer, Richard Goodman, and David Gortler. Defendants' Opposition brief does nothing to alter the fact that their experts seek to offer testimony that is inappropriate for the jury to hear and should be excluded.

I. INTRODUCTION

Defendants fail to counter Plaintiffs' argument that Drs. Schwartz, Katz, and Wei improperly base their opinions, regarding both the requisite level of substantiation for the challenged claims and the sufficiency of Defendants' substantiation, on their flawed interpretations of the law, rather than science. Defendants instead mischaracterize Plaintiffs' argument, cite inapposite case law, and—belatedly and ineffectively—attempt to argue that their experts' opinions were based on their scientific experience and judgment. The opinions of these experts attempting to identify and explain the relevant law, however, simply do not constitute "scientific knowledge" as required under *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), and should be excluded. Defendants also fail to show how the opinions of Drs. Schwartz, Katz, and Wei regarding FDA law are relevant.

Defendants additionally fall short in attempting to show that the erroneous opinions of their experts regarding the requisite level of substantiation would not confuse the jury. Defendants misread the language of the FTC's industry guide, "*Dietary Supplements: An Advertising Guide for Industry*" ("FTC Guidance" or "Guidance") and fail to distinguish the many cases requiring a randomized, controlled trial ("RCT") for dietary supplement claims. The opinions of Defendants' experts regarding a different standard, which are based on the experts' flawed understanding of the law, would serve only to confuse the jury.

Defendants also erroneously contend that experts in FTC cases are not asked to evaluate the competency or reliability of the evidence proffered to substantiate a claim, and that memory and cognition are not the relevant fields for this case. However, courts routinely rely on expert evidence to determine whether the proffered evidence is competent and reliable. Moreover, memory and cognition are the relevant fields because Defendants have advertised for years that Prevagen "improves memory" and provides other cognitive benefits.

Defendants' attempt to defend their manipulation of the Madison Memory Study's data, after the fact, through their experts, is unavailing and undermines any notion that they possess competent and reliable scientific evidence for the challenged claims. First, Defendants ignore Dr. Katz's admission that he "profess[es to have] no specific expertise" in an econometric re-analysis of the Madison Memory Study's data performed by their consulting economist, Dr. Howard Beales, during the pendency of this litigation. Second, Defendants overlook the fact that their biostatistics expert, Dr. Lee-Jen Wei, proposed an alternative statistical methodology to interpret the Madison Memory Study's results and then utterly failed to apply this methodology to his analysis of the study. Finally, Defendants would have this Court admit yet another alternative analysis of the Madison Memory Study by Dr. Mindy Kurzer, who admits she is not an expert in cognitive function and clinical significance and looks at trends in the study's data using her logic and common sense, which lack any standards. For these reasons, the Court should exclude Dr. Katz's opinions on Dr. Beales' econometric re-analysis, the alternative analyses proposed by Drs. Wei and Kurzer on the Madison Memory Study, and Dr. Kurzer's opinions relating to memory and cognition.

Defendants have also failed to explain why the majority of their proposed testimony regarding potential mechanisms of action for Prevagen has any relevance to this case. With the

exception of the testimony of Dr. Richard Goodman about his own study regarding apoaequorin, an active ingredient in Prevagen, Defendants' experts made no effort to tie their testimony regarding mechanisms of action for *other* drugs and compounds to *apoaequorin*, the compound at issue in this case. Their attempts to speculate that apoaequorin might work a particular way just because something else works that way would take the jury well afield of the issues in this case. This testimony, additionally, should be excluded as prejudicial because it implies that Prevagen might work a certain way when Defendants' experts have offered no evidence that it does. Additionally, testimony offered by Drs. Goodman and Gortler fall outside their expertise and should be excluded as unreliable.

II. DEFENDANTS' EXPERTS OFFER IRRELEVANT AND ERRONEOUS LEGAL OPINIONS

Defendants' argument that Drs. Schwartz, Katz, and Wei do not offer inappropriate (and flawed) legal opinions fails to effectively counter the central premise of Plaintiffs' motion: that the opinions of these purportedly scientific experts regarding the applicable "legal and regulatory framework," and what the law does (or does not) require to substantiate the challenged claims, do not constitute *scientific* knowledge, as required under *Daubert*. Defendants' Opposition brief unsuccessfully attempts to rebut Plaintiffs' arguments by mischaracterizing them, citing inapposite case law, and attempting half-heartedly—without any citations to the experts' reports or testimony—to reframe their experts' opinions as being based in science. Defendants, however, cannot escape the fact that their experts (1) repeatedly reference what they believe to be the relevant law and (2) state that they measured Defendants' substantiation, not against the standards of their scientific fields, but according to their incorrect understanding of the applicable legal standards. Because opinions identifying and explaining the relevant law are not scientific in nature and usurp the responsibilities of the Court, the Court must exclude them.

Defendants also fail to effectively refute Plaintiffs' argument that the opinions of their experts regarding FDA laws, regulations, and approval of prescription drugs are irrelevant. In their unsuccessful attempt to do so, Defendants blatantly mischaracterize the FTC Guidance by stating—notably without citation—that it "expressly incorporates FDA law." (Defs. Opp'n. (ECF No. 315) at 11.) The Guidance, in fact, does no such thing, and states expressly that the Dietary Supplement Health and Education Act ("DSHEA") does "not" apply to advertising. More importantly, however, Defendants fail completely to address Plaintiffs' cited case law, including from the Second Circuit, showing that FDA laws and regulations do not apply to advertising substantiation cases brought under the FTC Act (and parallel New York law).

Finally, Defendants do not effectively rebut Plaintiffs' contention that the erroneous legal opinions of Drs. Schwartz, Katz, and Wei would confuse the jury. Defendants once again misread the language of the FTC Guidance in attempting to show that the opinions of these experts regarding the necessity of an RCT are correct. Defendants, for example, appear to mistakenly believe that the Guidance's statement that various forms of evidence will be *considered* as substantiation means that all such evidence necessarily will be *credited*. The Guidance, in fact, articulates that the requisite level of substantiation depends on a number of factors, including what experts in the relevant scientific fields say is necessary. (Graham Decl. (ECF No. 225) Ex. F, FTC Guidance at QUI-FTCNY-00189211-12.) In this case, Plaintiffs' expert, Dr. Mary Sano—whose expertise in the relevant scientific fields is unchallenged—properly has opined that an RCT is required to support the challenged claims. Defendants' experts' opinions regarding a different standard, based on their erroneous understanding of the law, would serve only to confuse the jury.

A. Drs. Schwartz, Katz, and Wei Offer Inadmissible Legal Opinions

Defendants' rebuttal to Plaintiffs' argument that Drs. Schwartz, Katz, and Wei offer inappropriate legal conclusions fails to refute Plaintiffs' central argument: that Defendants' experts look to the law, rather than science, both to determine the level of support necessary for the challenged claims and to evaluate the sufficiency of Defendants' substantiation. The inevitable conclusion that Defendants' experts' opinions regarding the substantiation standard are not "scientific knowledge," as required by *Daubert* and FTC case law, is bolstered by the language of Defendants' own brief and their experts' own reports. Defendants, for example, repeatedly claim that the FTC Guidance—a document issued by FTC staff to help marketers comply with the law—is the appropriate standard against which their experts should measure Defendants' substantiation materials. Defendants state in their brief that Drs. Schwartz, Katz, and Wei "reviewed Quincy's scientific substantiation against a set standard—the FTC Guidance—and opined that Quincy's substantiation surpassed that standard." (Defs. Opp'n. (ECF No. 315) at 5; *see also id.* at 8 ("The FTC Guidance informed Dr. Schwartz's opinion that—after viewing 'the totality of the available evidence'—the Challenged Claims were supported by competent and reliable scientific evidence.").) Additionally, the portions of the expert reports that Defendants reference in their Opposition bolster, rather than refute, Plaintiffs' contention that Defendants' experts' opinions about one of the central issues in the case—whether Defendants were required to have a well-conducted RCT to support their claims—were based not on science, as required under *Daubert* and FTC case law, but on the experts' flawed understanding of the law as summarized in the Guidance. (*See, e.g.*, Graham Decl. (ECF No. 225) Ex. Z, Wei Rebuttal Report ¶ 14 ("The FTC Guidance makes clear that ["competent and reliable scientific evidence"] is <u>not</u> the same standard as required for drug trials.") (emphasis in original); Ex. P, Katz Rebuttal Report ¶ 20 ("The FTC's Guidance states that dietary

supplements are subject to a flexible substantiation standard that considers all forms of competent and reliable scientific evidence (including information literature review and animal studies), and does not require human clinical trials.").)[1]

Defendants thus make clear that their experts' opinions are not "scientific knowledge" that is grounded in the "methods and procedures of science," as required by *Daubert*, nor are they based on the standards of the relevant scientific fields, as required by FTC substantiation case law. *See Daubert*, 509 U.S. at 590; *Daniel Chapter One v. FTC*, 405 F. App'x 505, 506 (D.C. Cir. 2010); *FTC v. Roca Labs, Inc.*, 345 F. Supp. 3d 1375, 1387 (M.D. Fla. 2018); *FTC v. COORGA Nutraceuticals Corp.*, 201 F. Supp. 3d 1300, 1309 (D. Wyo. 2016). Rather, the opinions are based on a flawed understanding of what the relevant law requires (or doesn't require) to substantiate the claims at issue. The Court therefore should exclude them. *See FTC v. Wellness Support Network, Inc.*, No. 10-cv-04879-JCS, 2013 WL 5513332, at *10 (N.D. Cal. Oct. 4, 2013) (granting FTC's motion to exclude expert's testimony, as expert's "reliance on the regulatory scheme under the FDA, as opposed to scientific principles, to support his analysis does not satisfy *Daubert's* requirement that an expert must offer 'scientific knowledge.'")

Rather than address the merits of Plaintiffs' argument, Defendants attempt to mischaracterize it. For example, Defendants attempt to narrow the scope of Plaintiffs' attack on the legal opinions offered by Drs. Schwartz, Katz, and Wei by arguing that their opinions do not constitute "legal *conclusions*" or "attempts to instruct the jury" on how to decide the case or "how to fill out the verdict sheet." (Defs. Opp'n. (ECF No. 315) at 5, 7, 8 (emphasis added).)

[1] This opinion is shared by Dr. Schwartz. (*See* Graham Decl. (ECF No. 225) Ex. X, Schwartz Rebuttal Report ¶ 17 ("The FTC's Advertising Guide also does not require a placebo-controlled human clinical trial to substantiate dietary supplement structure-function claims.").)

While Defendants' experts do, in fact, offer impermissible legal *conclusions*,[2] Plaintiffs' argument is actually broader—namely, that these experts are offering impermissible opinions about the appropriate legal *standard*, i.e., the evidence necessary to substantiate the challenged claims. Dr. Schwartz, for example, has an entire section of his rebuttal report titled "Level of Evidence Required for Dietary Supplement Manufacturers to Substantiate Structure-Function Marketing Claims." (Graham Decl. (ECF No. 225), Ex. X, Schwartz Rebuttal Report at 3.) In that section, he opines that:

> The Dietary Supplement Health and Education Act (DSHEA) provides a framework for manufacturers to make structure-function claims on products that meet the definition for a dietary supplement product. . . . The very passage of DSHEA by Congress demonstrates that a different standard of review is being used to analyze dietary supplement substantiation (in contrast to the standard of review used to analyze disease claims made in connection with drug products).

(*Id.* ¶ 13.) Such opinions about the appropriate legal "framework" for claims and the relevant "standard of review" for dietary supplement substantiation are not scientific in nature, but rather inappropriate attempts to explain the law.[3] *See United States v. Stewart*, 433 F.3d 273, 311 (2d Cir. 2006) ("[A]n opinion that purports to explain the law to the jury trespasses on the trial judge's exclusive territory.")

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[2] Dr. Schwartz, for example, states "I am not aware of any current marketing claims, including the Challenged Claims, that could be considered *false or misleading* . . . ." (Graham Decl. (ECF No. 225), Ex. W, Schwartz Aff. Report ¶ 9 (emphasis added).) This constitutes an inappropriate opinion on the ultimate issue to be decided by the jury. *See United States v. Bilzerian*, 926 F.2d 1285, 1294 (2d Cir. 1991) ("Although an expert may opine on an issue of fact within the jury's province, he may not give testimony stating ultimate legal conclusions based on those facts.")

[3] In his deposition testimony, Dr. Schwartz opined further that DSHEA, the FTC Act, and the FTC Guidance set forth the relevant evidentiary "standard" for substantiating claims for dietary supplement products. (*See* Glennon Decl. Ex. A, Schwartz Tr. at 98:18-99:14; 100:22-102:17; 117:8-19 (discussing FTC Guidance); 123:25-124:5.)

Defendants also misleadingly claim that Plaintiffs argue that Drs. Schwartz, Katz, and Wei should not have referenced or considered the definition of "competent and reliable scientific evidence" in the FTC Guidance. (Defs. Opp'n. (ECF No. 315) at 5.) Although Plaintiffs contend that there was no need for these experts—who Defendants purportedly are proffering for their *scientific* expertise—to reference a document designed to assist marketers comply with the law, Plaintiffs do not argue that merely reviewing or considering the FTC Guidance renders the experts' opinions invalid. Reviewing or considering the FTC Guidance would be unobjectionable, so long as the experts had based their opinions on science, rather than their flawed understanding of the Guidance's explanation of the law. As set forth above, the experts did not.

Defendants mount a half-hearted attempt to characterize their experts' opinions as based on science, rather than the law. Specifically, they contend that the experts "did not abandon their professional experience, judgment and identities when they reviewed Quincy's substantiation," and that they analyzed Defendants' substantiation "through the lenses of their respective professions." (*Id.* at 9, 10.) Having educational degrees or experience in the relevant scientific fields, however, is not the same thing as setting forth the standards of those fields and measuring Defendants' substantiation against them. Proffered testimony "doesn't become 'scientific knowledge' just because it's uttered by a scientist; nor can an expert's self-serving assertion that his conclusions were 'derived by the scientific method' be deemed conclusive." *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995). While Drs. Schwartz, Katz, and Wei might be adequately credentialed scientists, they simply failed to opine on the standards of the relevant scientific fields and assess Defendants' substantiation against those standards.

Finally, the cases Defendants cite in support of their arguments are inapposite. Defendants cite numerous cases for the unremarkable proposition that experts may "reference" the law in rendering their opinions. Courts in the cited cases, however, distinguish between "references" to the law and inappropriate attempts to determine or instruct the jury as to the applicable law. *See, e.g.*, *Hangarter v. Provident Life & Acc. Ins. Co*., 373 F.3d 998, 1017 (9th Cir. 2004) (references to state statutory provisions, "none of which were directly at issue in the case" and which "were ancillary to ultimate issue of bad faith," did not "improperly usurp the court's role by instructing the jury as to the applicable law"); *United States v. Liew*, No. CR 11-00573-1 JSW, 2013 WL 6441259, at *8 (N.D. Cal. Dec. 9, 2013) (expert's cite to a portion of the legislative history of the relevant law (where the applicability of the law was not at issue) did not usurp the court's role to instruct the jury "on the applicable law"); *Voter Verified, Inc. v. Premier Election Sols., Inc*., No. 6:09-CV-1968-ORL-19, 2011 WL 87306, at *2, 4 (M.D. Fla. Jan. 11, 2011) (witness with both a J.D. and Ph.D., testifying as an expert "determining claim validity" in a patent infringement case, could set forth the legal definitions of a term without usurping the court's authority to determine applicable law); *Sancom, Inc. v. Qwest Commc'ns Corp*., 683 F. Supp. 2d 1043, 1055-56 (D.S.D. 2010) (holding that court first would determine the applicable law and that expert testimony on whether a telecom company had provided services in accordance with the law would be admissible only if court found there were disputed issues of material fact or terms with specialized meanings in telecom field).

In this case, Drs. Schwartz, Katz, and Wei go well beyond "referring" to the law. Instead, they attempt to both identify and explain the requirements of the relevant law by opining that: (1) the applicable substantiation standard is established by the FTC Guidance and DSHEA; and (2) pursuant to that legal authority, claims for dietary supplements do not have to be

substantiated by an RCT. Their opinions thus are inappropriate efforts to usurp this Court's authority.

The cases cited by Defendants are distinguishable in other ways, as well. For example, *The Medicines Co. v. Mylan Inc*., No. 11-CV-1285, 2014 WL 1758135 (N.D. Ill. May 2, 2014), involved a witness who was a patent attorney and former Patent and Trademark Office administrative judge, in addition to being a scientist, who was opining on whether a party's conduct constituted "inequitable conduct." *See id.* at *3-*4. Because the court was the trier of fact and was "fully aware of the law of inequitable conduct," the court could "disregard or curtail" the expert's testimony as necessary at trial. *Id.* at *6. In *Arlaine & Gina Rockey, Inc. v. Cordis Corp*., No. 02-22555-CIV, 2004 WL 5504978 (S.D. Fla. Jan. 5, 2004), the expert witness was an attorney who was "offered exclusively as an expert in patent law." *Id.* at *23-*24. The court allowed the proposed testimony, noting that the information "could be helpful to a jury to clarify the language of the claims as interpreted by the scientific experts." *Id.* at *24. The court also noted that the potential testimony "shall not include any exposition or opinion as to the legal issues in this case or patent law generally." *Id.* (citation omitted). By contrast, the instant case will be tried to a jury, and none of Defendants' experts has legal expertise or is being offered to opine on legal matters. Their proffered opinions regarding the appropriate legal standards and the requirements of the law therefore are wholly inappropriate.

Furthermore, the cases Defendants cite for their assertion that "courts routinely admit expert testimony regarding regulatory compliance" are wholly inapposite. In *In re Mirena IUD Prod. Liab. Litig.*, 169 F. Supp. 3d 396 (S.D.N.Y. 2016), a case involving negligence and strict liability under state law, the court found that the testimony of two experts regarding compliance with FDA regulations was appropriate because such compliance went to the reasonableness of

the defendant company's conduct. *Id.* at 467, 474. Furthermore, the court found that, because the ultimate issue for the jury involved liability under the state laws, and not violations of FDA regulations, testimony regarding compliance with the regulations would not usurp the court's role in explaining the law to the jury. *Id.* In *M.G. v. Bodum USA, Inc.*, No. 19-CV-01069-JCS, 2021 WL 718839 (N.D. Cal. Feb. 24, 2021), a products liability case, the court found that an expert's opinions based on Consumer Product Safety Commission regulations were not improper legal conclusions, stating that "[a]s a general rule, experts may refer to their understanding of the requirements of statutes and regulations *in offering testimony about industry norms and practices*." *Id.* at *17 (emphasis added). In this case, unlike the matters in *Mirena* and *Bodum*, the reasonableness of Defendants' conduct as shown by regulatory compliance or deviation from industry norms and practices is not at issue. The jury here simply must determine whether Defendants possessed sufficient substantiation for the challenged claims, an issue on which Defendants' purported compliance with FDA's regulatory scheme has no bearing.

The Court therefore should exclude the opinions of these experts identifying, discussing, or setting out the requirements of the relevant law.[4]

B. The Opinions of Drs. Schwartz, Katz, and Wei Regarding the FDA Are Irrelevant

In an effort to make the opinions of Drs. Schwartz, Katz, and Wei regarding FDA law appear relevant, Defendants again blatantly mischaracterize and cherry pick language from the FTC Guidance. More importantly, though, Defendants completely fail to address Plaintiffs' cited case law, including the Second Circuit case of *Bristol-Myers Co. v. FTC*, 738 F.2d 554 (2d

[4] The objectionable opinions addressed in this section of Plaintiffs' brief are found in the following paragraphs of the experts' reports: Graham Decl. (ECF No. 225), Ex. W, Schwartz Aff. Report ¶¶ 7, 9, 10, 13; Ex. X, Schwartz Rebuttal Report ¶¶ 3-26, 39-40, 45-46, 48-50; Ex. P, Katz Rebuttal Report ¶¶ 2, 6, 9-11, 18-36; Ex. Z, Wei Aff. Report ¶¶ 10-17, 22-24, 37, 42, 51-52, 55.

Cir. 1984), which makes clear that FDA laws and regulations simply do not apply to a claim substantiation case brought under the FTC Act (and, in this case, associated New York law).

Defendants patently mischaracterize the content of the FTC Guidance by asserting—notably, without any citation—that the Guidance "was enacted in response to DSHEA and *expressly incorporates FDA law*." (Defs. Opp'n. (ECF No. 315) at 11 (emphasis added).) As an initial matter, while FTC staff "issued" (rather than "enacted") the FTC Guidance to help address questions regarding dietary supplement advertising generated by DSHEA (and in light of the increased volume of such advertising following DSHEA's enactment), the Guidance specifically states that "FTC staff is issuing this guide to clarify how *long-standing* FTC policies and enforcement practices relate to dietary supplement advertising." (Graham Decl. (ECF No. 225) Ex. F, FTC Guidance at QUI-FTCNY-00189204 (emphasis added).) More critically, the FTC Guidance in no way "expressly incorporates FDA law." In fact, the Guidance does just the opposite, providing specifically that DSHEA does "not" apply to advertising. (*Id.* at QUI-FTCNY-00189204, QUI-FTCNY-00189206.) Defendants, unsurprisingly, fail to note or address this language of the Guidance.

More importantly, Defendants fail completely to address Plaintiffs' cited case law showing that FDA law is not relevant in an advertising substantiation case brought under the FTC Act. (*See* Pls. MOL (ECF No. 304) at 10-11 (citing *Bristol-Myers*, 738 F.2d at 559; *Thompson Med. Co. v. FTC,* 791 F.2d 189, 193 (D.C. Cir. 1986); *FTC v. Lunada Biomed.*, No. CV-15-3380-MWF, 2015 WL 12911515, at *4-*5 (C.D. Cal. Sept. 23, 2015); *Wellness Support Network*, 2013 WL 5513332, at *10.) In *Bristol-Myers*, the company argued that the FTC had no basis for requiring well-controlled clinical studies to support comparative safety claims. *Bristol-Myers*, 738 F.2d at 558-59. Citing the Food, Drug and Cosmetic Act and FDA regulations, the

company contended instead that the clinical study requirement should apply only to comparative efficacy claims. *Id.* The Second Circuit disagreed, stating first that the FTC, in establishing the order requirements, was entitled to rely on the testimony of an expert in gastroenterology and gastrointestinal side effects that only well-controlled clinical studies could establish safety superiority. *Id.* at 559. The court also rejected the company's FDA-based argument, stating that "[i]nsofar as FDA requirements and regulations are concerned, they simply do not govern this case." *Id.* In *Wellness Support Network*, the FTC moved to exclude the opinions of an expert witness that were based, in part, on the expert's understanding of the FDA's regulations relating to medical foods. *Wellness Support Network*, 2013 WL 5513332, at *10. The court granted the FTC's motion, stating that, even if the products at issue were considered medical foods by the FDA, "the degree of regulation they would be subjected to by the FDA simply is not relevant to the issues of this case." *Id.* (citing *Bristol-Myers*); *see also Lunada Biomed.*, 2015 WL 12911515, at *4-5 (FDA laws and regulations were inapplicable, even when the product at issue was a dietary supplement).

The above cases demonstrate that all opinions relating to FDA laws and regulations, as well as the approval of the prescription drug, Aduhelm, under the FDA framework, are not relevant in this case. Notably, Defendants acknowledge that the FDA's approval of Aduhelm—a drug intended to slow the progression of Alzheimer's disease—"may not be *directly* relevant to the substantiation of the Challenged Claims." (Defs. Opp'n. (ECF No. 315) at 12 (emphasis in original).) Their argument that the approval is even *somewhat* relevant—that the regulatory approval "reflects the nuanced and flexible approach the government takes with respect to product substantiation" (*Id.*)—fails in light of *Bristol-Myers*. Furthermore, Defendants do not even attempt to address Plaintiffs' argument that the opinions of Dr. Schwartz concerning the

substantiation proffered by other dietary supplement marketers are irrelevant. Such opinions simply have no bearing on whether Defendants in this case possessed sufficient substantiation for the claims at issue. *See* Fed. R. Evid. 401 (relevant evidence must relate to a fact "of consequence in determining the action").

Finally, Defendants contend that, because Plaintiffs "rely on" allegations in a 2012 FDA warning letter to Defendants, the Court should reject "Plaintiffs' blanket request to bar all references to the FDA," a request Plaintiffs did not make in their *Daubert* motion. (Defs. Opp'n. (ECF No. 315) at 11-12.) While Plaintiffs might seek to use the FDA warning letter for certain, limited purposes (*e.g.*, to counter Defendants' contention that the target market for Prevagen always has been healthy or mildly impaired (non-diseased) individuals), that does not mean that FDA laws or regulations—or any purportedly scientific opinions relating to or based on them—are relevant to any contested issue in this case. Furthermore, Plaintiffs are not asking the Court to "bar all references to the FDA." Rather, they seek the exclusion of purportedly scientific opinions discussing, and based on, FDA's statutes, regulations, guidance, or drug approvals, which, as set forth above, have no bearing on whether Defendants' claims were false or misleading under the FTC Act and New York law.[5]

[5] Additionally, there is no merit to Defendants' claim that Plaintiffs have failed to adequately specify the FDA-related opinions of Drs. Schwartz, Katz, and Wei that they seek to exclude. In Section III.B of their brief, Plaintiffs describe the objectionable opinions—and the bases for excluding them—in more than adequate detail. *See, e.g.*, Pls. MOL (ECF. No. 304) at 12 (seeking the exclusion of "all such opinions relating to FDA's DSHEA, other FDA statutes, regulations, guidance, or drug approvals, and the actions of other dietary supplement manufacturers"). Nonetheless, to provide even more clarity, the specific paragraphs of the experts' reports containing the objectionable opinions addressed in this section of Plaintiffs' brief are as follows: Graham Decl. (ECF No. 225) Ex. W, Schwartz Aff. Report ¶¶ 7, 9-10, 28, 67; Ex. X, Schwartz Rebuttal Report ¶¶ 3-11, 13, 15, 19-20, 22-26, 28-29, 39-40, 44, 46-47, 49-50; Ex. P, Katz Rebuttal Report ¶¶ 6, 9-11, 19, 21-26, 29, 31-36; Ex. Z, Wei Aff. Report ¶¶ 10-14, 16-17, 37, 42, 51.

C. The Erroneous Opinions of Drs. Schwartz, Katz, and Wei Regarding the FTC Act and Guidance Would Only Confuse the Jury

Defendants' argument that the erroneous legal opinions of Drs. Schwartz, Katz, and Wei would not confuse the jury is based on their—and their experts'—selective reading and fundamental misunderstanding of the FTC Guidance. Defendants argue that their experts' opinions that an RCT is not needed to substantiate the challenged claims are based on the fact that the Guidance does not limit the evidence that "can be *considered*" to an RCT. (Defs. Opp'n. (ECF No. 315) at 13.) They argue further that their experts followed the Guidance's "totality-of-the-evidence approach to a tee." (*Id*.) Defendants appear to mistakenly believe that the fact that various types of evidence may be *considered* means that all types of evidence automatically will be *credited*. Relatedly, Defendants also appear to believe that the FTC Guidance's advice that marketers should consider the "totality of evidence" relating to their claim means that "anything goes" in terms of what counts as substantiation. In essence, Defendants' position appears to be that, given the Guidance's reference to a "flexible standard," any type of substantiation proffered by a marketer will count for at least something, so that even if each individual piece doesn't constitute "competent and reliable scientific evidence," accumulating enough pieces of subpar substantiation can allow the marketer to reach that threshold of evidence. This simply is not the case. As the FTC Guidance itself states, the requisite level of substantiation depends on a number of factors, including what experts in the relevant scientific fields believe to be necessary. (Graham Decl. (ECF No. 225) Ex. F, FTC Guidance at QUI-FTCNY-00189211-12.) In this matter, Dr. Sano—whose expertise in the relevant scientific fields of memory, cognition, and clinical trials is undisputed—has opined that an RCT is necessary, and that other forms of evidence, such as open label and animal studies, are insufficient to demonstrate efficacy in humans. (Soberats Decl. (ECF No. 258) Ex. A, Sano Aff. Report ¶¶ 28-29, 41-42; Ex. B, Sano

Rebuttal Report ¶¶ 3.e-f, 14.)[6] Defendants' experts' opinions regarding a different, and incorrect, standard of evidence would serve only to confuse the jury.

Defendants fail to distinguish cases cited by Plaintiffs holding that dietary supplement claims had to be substantiated by an RCT. Defendants argue that the cited cases either (1) involved disease claims; or (2) involved cases where the marketers proffered "little to no" substantiation. (Defs. Opp'n. (ECF No. 315) at 13 n.3.) While some of Plaintiffs' cited cases involved disease claims, not all did,[7] and none of the cases involving disease claims held that an RCT was appropriate only for such claims. Furthermore, the fact that the cited cases imposed an RCT requirement on claims for dietary supplement products undermines the argument of Defendants (and their purported scientific experts) that such a "drug-level" of evidence does not apply to dietary supplement products. (*Id.* at 13.) Defendants' second proffered basis for distinguishing the cases is simply nonsensical. Not surprisingly, Defendants have offered no explanation of why courts would impose an RCT requirement when marketers' proffered substantiation was particularly weak.

Finally, Defendants again obfuscate in attempting to rebut Plaintiffs' argument that Defendants were required to have an RCT because their advertising specifically claimed that level of proof. (*Id.* at 14.) Defendants' first contention—that they in fact did have an RCT (the Madison Memory Study)—fails to address Plaintiffs' argument that an RCT is the requisite standard. Second, Defendants' assertion that Plaintiffs somehow cannot argue the meaning of

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[6] Additionally, despite opining on the necessity of an RCT, Dr. Sano actually did *consider* Defendants' non-RCT evidence, finding it to be flawed and inadequate to support the challenged claims. (*See* Soberats Decl. (ECF No. 258) Ex. A, Sano Aff. Report ¶¶ 15-16, 29, 117-20; Ex. B, Sano Rebuttal Report ¶¶ 3.f, 14-17, 19.)

[7] *E.g.*, *COORGA Nutraceuticals Corp.*, 201 F. Supp. 3d at 1305 (involving claim that dietary supplement "reverses or prevents the formation of gray hair").

"clinically proven" because Plaintiffs did not submit consumer perception evidence of the phrase misunderstands Plaintiffs' burden and case law regarding claim interpretation and substantiation. In cases such as this one, where marketers make express or strongly implied claims, the trier of fact may determine whether advertisements make the challenged claims without resorting to extrinsic evidence of consumer perception. *FTC v. Bronson Partners, LLC*, 564 F. Supp. 2d 119, 125-28 & n.8 (D. Conn. 2008); *FTC v. Nat'l Urological Grp*, 645 F. Supp. 2d 1167, 1188-89 & n.12 (N.D. Ga. 2008). Furthermore, when marketers claim a specific type of substantiation, they must possess the type of evidence claimed. *Roca Labs.*, 345 F. Supp. 3d at 1388 (noting that an establishment claim is required to have the level of proof claimed in the ad); *FTC v. Wellness Support Network, Inc.*, No. 10-cv-04879-JCS, 2014 WL 644749, at *16 (N.D. Cal. Feb. 19, 2014) (finding that "for establishment claims advertisers must have the level of substantiation referenced in the claim itself" and applying this standard to advertising claims that referenced clinical and scientific studies). In this case, Defendants' ads repeatedly have stated that "clinical trials" and, even more specifically, an RCT, prove Prevagen's efficacy.[8] Having made such express and strongly implied claims about an RCT, Defendants were required to possess such a study.[9]

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[8] *See, e.g.*, Olson Decl. (ECF No. 224) Ex. D, Prevagen "Clinically Tested" "Improves Memory" Product Packaging (claiming "In a computer assessed, double-blinded, placebo controlled study, Prevagen improved memory significantly."); Ex. E, Prevagen "Clinically Tested Ingredient" "Improves Memory" Regular Strength Product Packaging (claiming "In a computer-assessed, double-blinded, placebo-controlled clinical study, Prevagen improved certain aspects of cognitive function over a 90 day period."); Ex. F, Prevagen "Improves Memory" Extra Strength Product Packaging (claiming "In a computer assessed, double-blinded, placebo-controlled clinical study, Prevagen improved certain aspects of cognitive function over a 90-day period.").

[9] The objectionable opinions addressed in this section of Plaintiffs' brief are found in the following paragraphs of the experts' reports: (Graham Decl. (ECF No. 225) Ex. W, Schwartz

For the foregoing reasons, the Court should exclude the opinions of Drs. Schwartz, Katz, and Wei as requested in Plaintiffs' opening Memoradum and herein.

III. EXPERTS DO EVALUATE THE COMPETENCY AND RELIABILITY OF SUBSTANTIATION UNDER FTC LAW

Defendants argue that Plaintiffs "fail to cite a single case in which the expert was asked to evaluate the competency or reliability of evidence proffered to substantiate marketing claims." (Defs. Opp'n. (ECF No. 315) at 26.) However, the cases cited by Plaintiffs demonstrate that is precisely the role of experts in deceptive advertising cases. For example, in *Nat'l Urological Group*, the court relied on expert testimony to determine that a randomized clinical trial was required to support the claims, and that there was no evidence that the active ingredients provided the advertised weight loss. (*See* Pls. MOL (ECF No. 304) at 12, 21 (citing also *COORGA Nutraceuticals Corp.*, 201 F. Supp. 3d 1300 (relying on expert evidence showing that the defendants' observational study did not prove the product's efficacy because it had "numerous deficiencies"), *Roca Labs, Inc.*, 345 F. Supp. 3d 1375 (stating that the FTC's expert had "determined that the [defendants'] trial did not provide any competent or reliable scientific evidence because the trial design was flawed"), and *FTC v. NPB Adver., Inc.*, 218 F. Supp. 3d 1352 (M.D. Fla. 2016) (relying on expert evidence that discredited the studies proffered by defendant).) Additionally, in *FTC v. Alcoholism Cure Corp.*, which Defendants cited, the court relied on an expert who evaluated the reliability and competency of the proffered substantiation. (*See* Defs. Opp'n. (ECF No. 315) at 5; *FTC v. Alcoholism Cure Corp.*, No. 3:10–cv–266–J–34JBT, 2011 WL 13137951, at *36 (M.D. Fla. Sept. 16, 2011) (noting that the FTC's expert concluded that the trial "involved an insufficient number of subjects to measure an intervention;

Aff. Report ¶ 10; Ex. X, Schwartz Rebuttal Report ¶¶ 3-4, 6, 8, 10, 13-19, 21, 39-40, 49-50; Ex. P, Katz Rebuttal Report ¶¶ 9, 19-24, 26, 35-36; Ex. Z, Wei Aff. Report ¶¶ 10-17, 37, 42, 51-52, 55.)

did not employ reasonable and standard measures at designated points during and after the treatment period; did not involve a sufficiently long trial period or follow-up; and did not employ the standard scientific approach to data analysis").)[10]

Defendants' argument is also undermined by the very same FTC Guidance that they rely on. The Guidance notes that the proffered scientific evidence "is assessed to determine whether there is adequate support for [the] claims."[11] (Graham Decl. (ECF No. 225) Ex. F, FTC Guidance at QUI-FTCNY-00189206, 00189215 (discussing principles related to evaluating the quality of the evidence).) Both FTC cases and FTC Guidance show that experts in the relevant fields routinely evaluate the competency and reliability of the proffered substantiation.

IV. MEMORY AND COGNITION ARE THE RELEVANT SCIENTIFIC FIELDS

Contrary to Defendants' argument, memory and cognition are the relevant fields for determining Prevagen's purported efficacy because the facts establish that Defendants advertised that Prevagen improves memory and provides cognitive benefits.[12] (*See*, *e.g.*, Compl. Exs. A, C; Ducklow Decl. (ECF No. 260) Attachment 1, Prevagen.com at FTC-0000139.0003-04; Olson

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[10] Case law under the FTC Act is given great weight in construing the New York consumer protection statutes at issue in this case. *See In re People v. Applied Card Sys., Inc.*, 27 A.D.3d 104, 105 (3d Dep't 2005), *aff'd on other grounds*, 11 N.Y.3d 105 (2008) (explicitly "recognizing that the interpretations of the Federal Trade Commission Act (*see* 15 U.S.C. § 45 et seq.) are useful in determining the aforementioned violations under both the Executive Law and General Business Law"); *State v. Feldman*, 210 F. Supp. 2d 294, 302 (S.D.N.Y. 2002); *Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank*, 85 N.Y.2d 20, 26 (1995); *State v. Colorado State Christian Coll. of Church of Inner Power, Inc.*, 76 Misc. 2d 50, 54 (N.Y. Sup. Ct. 1973).

[11] In this case, the parties' experts offer competing opinions on whether there is competent and reliable scientific evidence to support the Challenged Claims, which makes summary judgment inappropriate. (*See* Pls.' Opp'n. to Defs. Mot. for Summ. J. (ECF No. 254) at 21-29.)

[12] For other issues in this case, such as how the SUR analysis or other statistical analyses of the Madison Memory Study were conducted, or Prevagen's purported mechanism of action, other fields of expertise would be applicable.

Decl. (ECF No. 224) ¶¶ 28-30, Ex. E, Prevagen product labels, at QUI-FTCNY-00013352; *see also* Pls. Opp'n. to Defs. Mot. for Summ. J. (ECF No. 254) at 6-8.)

For Dr. Kurzer, Defendants assert that it would be too narrow to define the relevant field as memory and cognitive function. (Defs. Opp'n. (ECF No. 315) at 24-25.) However, this argument is contrary to legal precedent and unsupported by the facts. To determine what would constitute competent and reliable scientific evidence based on the claims, courts look to experts in the relevant field. *See, e.g.*, *Daniel Chapter One*, 405 F. App'x at 506; *COORGA Nutraceuticals*, 201 F. Supp. 3d at 1309; *Alcoholism Cure Corp.*, 2011 WL 13137951, at *27; *Nat'l Urological Grp.*, 645 F. Supp. 2d at 1186. The relevant field is based on what claims were made. *Nat'l Urological Grp.*, 645 F. Supp. 2d at 1186 (stating that the competent and reliable scientific evidence standard "is context specific and permits different variations . . . *depending on what pertinent professionals would require for the particular claim made*" (emphasis added)).

Defendants' reliance on *United States v. Bayer*, No. 07-01, 2015 WL 1969300, at *5 (D.N.J. Apr. 30, 2015), and *FTC v. Your Baby Can LLC*, No. 12-cv-2114, 2014 WL 12789110, at *3 (S.D. Cal. Mar. 18, 2014), is unavailing because these cases show that the relevant field is based on the claims made. In *Bayer*, because the case involved whether the product at issue "defends against occasional constipation, diarrhea, and gas and bloating, or . . . prevents, cures or treats those symptoms," the court declined to exclude an expert who was a "gastroenterologist with extensive experience in testing the effectiveness of proposed treatments for gastrointestinal issues." *Bayer*, 2015 WL 1969300, at *5 (internal quotation marks omitted). Similarly, the *Your Baby Can* court declined to exclude plaintiff's expert because he had "expertise in early literacy development and language acquisition covering the age range of birth through age five," and therefore could opine on claims about the efficacy of the defendants' infant and child learning

program. *Your Baby Can*, 2014 WL 12789110, at *3. *Bayer* and *Your Baby Can* found that the experts' expertise fit the claims at issue. *Bayer*, 2015 WL 1969300, at *5; *Your Baby Can*, 2014 WL 12789110, at *3-4. Based on Defendants' advertising claims, memory and cognition are the relevant fields to determine whether Prevagen improves memory or provides other cognitive benefits.[13]

V. DR. KATZ IS UNQUALIFIED TO OPINE ON DEFENDANTS' *POST HOC* SUR RE-ANALYSIS

Defendants' Opposition brief does not overcome the reality that Dr. Katz is wholly unqualified to evaluate the seemingly unrelated regressions ("SUR") re-analysis of the Madison Memory Study performed by Defendants' consulting expert, Dr. Howard Beales, and two economists from Georgetown Economic Services, a subsidiary of Kelley Drye, counsel for Corporate Defendants. Defendants continue to overlook Dr. Katz's very clear concession that as to the SUR model, he "profess[es to have] no specific expertise in this analytical method." (*See* Pls. MOL (ECF No. 304) at 15-16.) Because Dr. Katz lacks experience in econometrics and has admitted that he is not an expert on the SUR model, his opinions regarding Defendants' SUR re-analysis are "inherently unreliable" and should be excluded. *See In re Rezulin Prod. Liab. Litig.*, 309 F. Supp. 2d 531, 549 (S.D.N.Y. 2004); *see also In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d at 477.

Defendants appear to acknowledge that Dr. Katz lacks "specific experience with econometrics and/or the SUR method . . . ." (Defs. Opp'n. (ECF No. 315) at 16.) Indeed, their Opposition brief does not describe any experience Dr. Katz has in this field or with this econometric model. In addition, Dr. Katz testified that he "profess[es to have] no specific

[13] These would be the relevant fields when determining whether any of Defendants' experts, including Drs. Kurzer, Katz, Schwartz, Alexander, or Gortler, are qualified to opine on whether Prevagen improves memory or provides other cognitive benefits.

expertise" in the SUR model, and it is a "technique [he] had never used and do[es] not know intimately." (Pls. MOL (ECF No. 304) at 15-16.) Defendants also do not appear to dispute that the bases of Dr. Katz's opinions on Defendants' SUR re-analysis were conversations he had with Dr. Beales, that those conversations were "certainly not a tutorial in how to conduct [the SUR analysis] independently," and that Dr. Katz "was guided in this particular matter by [Dr. Beales'] expertise." (*Id*.)

Defendants' contention that Dr. Katz is qualified to evaluate the SUR re-analysis because he has experience in biostatistics, epidemiology, preventative medicine, and public health is wholly unpersuasive (Defs. Opp'n. (ECF No. 315) at 14-15, & n.5.) Experience in these fields does not provide the specialized knowledge that is necessary to evaluate Dr. Beales' SUR re-analysis, "the soundness of [which] is in issue." *See Dura Auto. Sys. of Ind., Inc. v. CTS Corp*, 285 F.3d 609, 613 (7th Cir. 2002). Indeed, the critical issues as to the SUR re-analysis of the Madison Memory Study are (1) whether it was properly programmed, and (2) if it was properly programmed, whether it yielded statistically significant results. Plaintiffs' expert in economics, econometrics, and statistics, Dr. Peter Malaspina, opined that Dr. Beales programmed his purported SUR re-analysis in such a way that it violates the assumptions of a SUR model because it does not account for the correlations in the study's data. (*See* Graham Decl. (ECF No. 308) Ex. L, Malaspina Aff. Report ¶¶ 6-42.) Dr. Katz, who admits he has never used the SUR model before and does not know it "intimately", is not competent to opine on the first issue,[14]

[14] While Defendants make much of the fact that Dr. Katz "taught biostatistics courses" and "went on to become the course director in biostatistics for Yale medical students for roughly a decade" (Defs. MOL (ECF No. 315) at 15), Dr. Katz candidly testified that he did not teach the SUR method in his biostatistics courses and did not recall ever encountering the SUR method while undergoing his Master's of Public Health program. (Matuschak Decl. (ECF No. 305) Ex. A, Katz Tr. 29:8—30:2.)

and, therefore, cannot "provide conclusions that depended on the modeling he had not and could not himself competently perform." *In re M/V MSC Flaminia*, No. 12-cv-8892 (KBF), 2017 U.S. Dist. LEXIS 119146, at *176 (S.D.N.Y. July 28, 2017) (citing *Dura*, 285 F.3d at 614) ("While Dura's proposed expert could testify as to the area he was an expert in, he could not provide conclusions that depended on the modelling he had not and could not himself competently perform."). Without an expert opinion on the first issue—whether Dr. Beales' SUR re-analysis was properly programmed—Defendants cannot prevail on the second—whether it yielded statistically significant results. *See Dura*, 285 F.3d at 615 (excluding expert testimony where it was apparent expert's "assistants did not merely collect data for him to massage or apply concededly appropriate techniques in a concededly appropriate manner, or otherwise perform routine procedures and that [the expert] himself lack[ed] the necessary expertise to determine whether the techniques were appropriately chosen and applied").

As Dr. Malaspina's expert report illustrates, constructing a valid SUR model, determining whether the chosen techniques were appropriately applied, and interpreting the model's results requires "the exercise of sound technical judgment," "[i]n other words, professional discretion—expertise—is involved." *See id.* at 614; *see also* Graham Decl. (ECF No. 308) Ex. L, Malaspina Aff. Report ¶¶ 6-21, 24-42, Exs. 3.1-4.2.). Dr. Katz lacks the specialized education, knowledge, and experience that would afford him this professional discretion. *See Dura*, 285 F.3d at 614. Indeed, "the process of constructing a valid [SUR] model is an iterative process that requires the exercise of sound technical judgment in evaluating all available . . . data to determine what input values should be used with respect to each parameter utilized in the model." *See id.* Here, it was Dr. Beales who constructed the SUR model, and the iterative process Dr. Beales employed in constructing his model is beyond the scope of Dr.

Katz's expertise.[15] *See id*. at 615. At best, Dr. Katz can only repeat Dr. Beales' findings on the SUR re-analysis and present them as his own, which is precisely what he has done here.

Indeed, Dr. Katz's testimony revealed that he did not verify Dr. Beales' conclusions about the SUR re-analysis. When Dr. Katz was asked whether he agreed that the F values reported by Dr. Beales did not indicate whether Prevagen outperformed placebo or vice versa, Dr. Katz responded that he "would have to spend a lot more time working on the details of these tables" and could not give Plaintiffs an answer. (Matuschak Decl. (ECF No. 305) Ex. A, Katz Tr. 207:17-25.) "A failure to validate data by itself can constitute grounds for excluding an expert report." *Forte v. Liquidnet Holdings, Inc.*, 675 Fed. App'x 21, 24 (2d. Cir. 2017) (citing *Munoz v. Orr*, 200 F.3d 291, 301-02 (5th Cir. 2000)) (noting that an expert's reliance on data provided by a plaintiff, without conducting independent verification, gives rise to "common-sense skepticism" regarding the expert's evaluation). Defendants' argument that Dr. Katz "did not blindly accept Dr. Beales' conclusions" contradicts Dr. Katz's foregoing testimony and Dr.

[15] In support of their argument that Dr. Katz is qualified to evaluate Dr. Beales' SUR re-analysis, Defendants claim that "Dr. Katz was trained in the SAS programming language used in Dr. Beales' SUR analysis" (Defs. Opp'n. (ECF No. 315) at 15), but this is not what Dr. Katz stated during his deposition. While Dr. Katz did testify that he was "trained in SAS programming language," he did not testify that he was trained in the specific SAS programming instructions Dr. Beales employed in his SUR re-analysis. (Matuschak Decl. (ECF No. 305) Ex. A, Katz Tr. 29:1-7.) As Plaintiffs noted in their Opposition to Defendants' Motion to Exclude Plaintiffs' Experts, the SAS System User Guide is often revised, is thousands of pages long, and covers numerous programing instructions. (Pls. Opp'n. (ECF No. 313) at 23.) Indeed, the SAS System Software is used by various disciplines to conduct many varied analyses. Expertise in the use of SAS to apply biostatistical techniques does not translate into expertise in the use of SAS to apply econometric techniques. There is nothing in the record evidencing that Dr. Katz was trained on programming language specific to a SUR analysis or any other econometric analysis. Furthermore, SAS is merely a tool for processing data. Even if Dr. Katz had familiarity with SAS instructions related to the SUR model, which he does not, such knowledge would not be sufficient on its own to deem Dr. Katz an expert on the SUR model. Such expertise is gained from having studied the SUR model through, typically, graduate studies in econometrics. Dr. Katz never pursued such graduate studies.

Katz's own acknowledgement that in reaching his primary conclusion on the SUR re-analysis—that it "produces decisively significant results for those study participants without overt cognitive impairment"—he relied upon Dr. Beales' re-analysis and "additional guidance from Dr. Beales to help me understand it." (Matuschak Decl. (ECF No. 305) Ex. A, Katz Tr. 208:9-22.)[16]

Defendants argue that if Plaintiffs' biostatistics expert, Dr. Janet Wittes, who admits that she "had no experience with a SUR analysis" prior to this case can opine on the SUR re-analysis, then so can Dr. Katz. (Defs. Opp'n. (ECF No. 315) at 16.) Defendants' argument rings hollow, however, because Dr. Wittes, unlike Dr. Katz, carefully limited her report only to those SUR opinions for which she is qualified – the F test Dr. Beales used to evaluate the joint statistical significance of the Madison Memory Study's outcomes. (Graham Decl. (ECF No. 308) Ex. G, Wittes Rebuttal Report ¶¶ 4, 19.) As stated earlier, Dr. Katz admitted to being unable to interpret the F test results reported by Dr. Beales.

Because Dr. Katz's expert report "simply repeats the findings of [Dr. Beales] and proffers them as his own despite his lack of qualifications in the relevant field[s]," his opinions relating to Dr. Beales' SUR re-analysis should be excluded.[17] *In re M/V MSC Flaminia*, 2017 U.S. Dist. LEXIS 119146, at *228 (excluding expert testimony where expert admitted at his deposition that he lacked expertise in relevant fields, "simply repeat[ed] the findings of other experts[,] and

[16] To detract from Dr. Katz's lack of qualifications, Defendants devote almost an entire page of their Opposition brief to restating their meritless *Daubert* challenge as to Plaintiffs' expert, Dr. Malaspina. (Defs. Opp'n. (ECF No. 315) at 16, 18.) Dr. Malaspina is more than qualified to opine on Defendants' SUR re-analysis; he neither conceded that his analysis was unreliable nor abandoned his opinions at his deposition, as Defendants misrepresent. (Pls. Opp'n. (ECF No. 313) at 16-30.)

[17] Dr. Katz's opinions relating to Dr. Beales' SUR re-analysis are contained in Paragraphs 35-37 of Dr. Katz's affirmative report dated April 22, 2021. (Graham Decl. (ECF No. 225) Ex. O, Katz Aff. Report.)

proffer[ed] them as his own"; "[w]hile the [expert] may rely upon the reports of others in developing and presenting his own opinions, he cannot simply present the opinions of others—he must let them speak for themselves.").

VI. DR. WEI FAILED TO APPLY HIS STATED METHODOLOGY RELIABLY TO HIS ANALYSIS OF THE MADISON MEMORY STUDY

Defendants do not appear to dispute that their biostatistics expert, Dr. Wei, failed to apply the statistical methodology he proposed for the Madison Memory Study. Instead, Defendants state that because Dr. Wei did not purportedly opine that his statistical methodology was "necessary," Second Circuit case law does not warrant exclusion of his incomplete analysis. (Defs. Opp'n. (ECF No. 315) at 19-22.) The Court should reject Defendants' attempt to retroactively reframe Dr. Wei's expert report and testimony and should exclude his partial analysis of the Madison Memory Study. The record here is clear. Dr. Wei criticized Plaintiffs' experts for using a Type I error rate of $p<0.05$ to evaluate the statistical significance of the Madison Memory Study's results. (Pls. MOL (ECF No. 304) at 17-18.) He proposed an alternative statistical methodology that he opined was needed for this case and then failed to apply his own stated methodology to his analysis of the study. (*Id*. at 17-21.) Instead, Dr. Wei selectively reported results that would not allow the jury to determine whether the Prevagen group outperformed the placebo group, or vice versa, or whether there was no difference between the groups. (*Id*. at 19.) On this record, exclusion of Dr. Wei's analysis of the Madison Memory Study is more than justified.

In *Amorgianos v. Amtrak*, 303 F.3d 256, 268-70 (2d Cir. 2002), the Second Circuit excluded expert testimony where plaintiffs' expert, like Dr. Wei, failed to apply his own methodology reliably regarding the xylene concentration to which Amorgianos was exposed. There, plaintiffs' industrial hygienist expert testified that a "*proper* exposure assessment" for the

evaporation rate of a solvent from paint depended on certain variables. *Id.* at 268 (emphasis added). The Second Circuit upheld the district court's exclusion of the expert's opinion because "[i]n reaching his conclusion about [Amorgianos's] exposure," the expert "did not include any of these variables in his calculations." *Id*. Instead, "[a]lthough data on the additional variables was available to [plaintiffs' expert], he inexplicably 'did not find it necessary' to include them in his calculation despite his stated opinion that a 'proper exposure assessment' would take them into consideration." *Id*. The Second Circuit concluded that "[b]ecause [the expert's] opinion rested on a faulty assumption due to his failure to apply his stated methodology 'reliably to the facts of the case,'" the expert's opinion "regarding the xylene concentration to which Amorgianos was exposed was not based on 'good grounds.'" *Id*. at 269.

Contrary to Defendants' assertions, the facts of this case are remarkably similar to those of *Amorgianos*. Like the expert in *Amorgianos*, Dr. Wei proposed what he believed was a proper statistical methodology for the Madison Memory Study. (Pls. MOL (ECF No. 304) at 17-21.) Indeed, Dr. Wei opined that, "[r]ather than rely on the outdated and meaningless 'bright line' rule of $p<0.05$ to assess the significance of the Madison Memory Study," "*[f]or this case, we need* to quantify the totality of evidence on the treatment effect with all the [Madison Memory Study's] multiple outcomes simultaneously, not on a single endpoint." (Graham Decl. (ECF No. 225) Ex. Z, Wei Rebuttal Report ¶¶ 23-24) (emphasis added).) He observed, "It is *important* to use the data from [the Madison Memory Study's] nine outcomes all together for making statistical inferences" and stated that this methodology, which involved performing several calculations, "has been discussed extensively in various papers," including one that he co-authored in 2020. (*Id*. ¶ 25 (emphasis added).) Dr. Wei did not perform any of the calculations in his 2020 paper when he analyzed the Madison Memory Study. Instead, Dr. Wei did an

incomplete analysis, which he conceded does not answer the question of whether the Prevagen group outperforms the placebo group, or vice versa, or whether there is no difference between the groups. (Pls. MOL (ECF No. 304) at 19.)

Dr. Wei's analysis has the same fatal flaw as the analysis of the expert in *Amorgianos*. Dr. Wei described his methodology as "important" and "need[ed]" for this case but failed to perform any of the calculations when analyzing the Madison Memory Study even though he or Defendants had access to the information needed to perform them. (*See id.* at 17-20.) In light of Dr. Wei's failure to apply the calculations he deemed proper, and his acknowledgement that the calculations he did perform do not answer the question of whether Prevagen outperforms placebo, the Court should exclude Dr. Wei's opinion as unreliable.[18]

Even if it were true that Dr. Wei did not opine that his analysis was "necessary," as Defendants argue, his testimony would still be inadmissible. The expert in *Amorgianos* opined that certain variables were to be considered for a "proper" analysis. As stated above, the Second Circuit excluded that expert's analysis because he failed to consider those variables and thus, his methodology was not applied reliably to the facts of the case. Dr. Wei committed the same fatal error in this case by not conducting an analysis that he stated was "important" and "need[ed]" for this case, and for this reason, his analysis of the Madison Memory Study should be excluded.

Defendants also miss the mark when they attempt to distinguish *Amorgianos* by arguing that, unlike the plaintiffs in *Amorgianos*, they "do[] not bear the burden of proof and therefore

[18] The fact that Dr. Wei proposed a second statistical methodology for the first time at his deposition—calculation of a composite score for the Madison Memory Study's nine outcome measures—does not salvage his unreliable testimony, as Defendants argue. (Defs. Opp'n. (ECF No. 315) at 20-21.) Dr. Wei also failed to apply this second statistical methodology. (Graham Decl. (ECF No. 316) Ex. B, Wei Tr. 185:14—187:12.)

Dr. Wei was not required to conduct his own statistical analysis of the Madison Memory Study. . . ." (*Id.* at 22.) Defendants overlook the fact that they, as the proponents of Dr. Wei's expert testimony, *do* bear the burden of establishing the admissibility of Dr. Wei's testimony by a preponderance of the evidence. *See Arista Records LLC v. Usenet.com, Inc*., 608 F. Supp. 2d 409, 422 (S.D.N.Y. 2009) (quoting *United States v. Williams*, 506 F.3d 151, 160 (2d Cir. 2007)). Defendants cannot meet this burden due to Dr. Wei's failure to apply his stated methodology "reliably to the facts of the case." *See Amorgianos*, 303 F.3d at 269. In light of Dr. Wei's failure to apply the calculations he deemed proper, and his acknowledgement that the calculations he did perform do not answer the question of whether Prevagen outperforms placebo, the Court should exclude Dr. Wei's analysis of the Madison Memory Study as unreliable.[19]

VII. DR. KURZER IS UNQUALIFIED TO OPINE ON MEMORY AND COGNITION

Plaintiffs seek to exclude Dr. Kurzer's testimony related to memory and cognition because she is unqualified. (Pls. MOL (ECF No. 304) at 21-25.) Defendants argue that they "are not offering Dr. Kurzer as an expert on memory and cognition or on Prevagen's clinical significance" and that Dr. Kurzer is qualified to opine on memory and cognition claims because she is a scientist who has "extensive experience in designing, conducting, analyzing, and evaluating clinical trials involving dietary supplements and dietary ingredients." (Defs. Opp'n. (ECF No. 315) at 3, 23.) While they claim to not offer Dr. Kurzer as an expert on memory or cognition, this assertion is belied by her report, which is replete with opinions concerning memory and cognition. (*See* Pls. MOL (ECF No. 304) at 21-22; *see, e.g.*, Graham Decl. (ECF No. 225) Ex. R, Kurzer Aff. Report ¶¶ 19-35, 48-52 (including Tables 1 and 2), 60-84 (including

[19] Dr. Wei's inadmissible alternative analysis of the Madison Memory Study is contained in paragraphs 23-30, 41, 43, 53 and Tables 1-2 of his rebuttal report dated July 16, 2021. (Graham Decl. (ECF No. 225) Ex. Z, Wei Rebuttal Report.)

opinions related to "Cognitive Function and Cognitive Impairment," "Evaluation of Cognitive Function," "Treatment Options for Cognitive Impairment," "Evidence of the Effects of AQ/Prevagen on Brain Function and Memory: In Vitro and Animal Studies," and "Evidence of the Effects of AQ/Prevagen on Brain Function and Memory: Human Clinical Studies").) Defendants' attempt to describe her extensive opinions on "Cognitive Function and Cognitive Impairment," "Evaluation of Cognitive Function" and "Treatment Options for Cognitive Impairment" as "background sections that set the stage for her subsequent opinions regarding Quincy's substantiation" is unavailing. (Defs. Opp'n. (ECF No. 315) at 24 n.9.) It is inexplicable how "background sections" on cognitive function, impairment, and treatment could "set the stage" for Dr. Kurzer's opinions on the substantiation, yet the relevant fields, according to Defendants, are not memory and cognition.[20] *See supra* Section IV (discussing that memory and cognition are the relevant fields).

Opinions on whether Prevagen improved memory or cognition are beyond Dr. Kurzer's knowledge and experience.[21] Dr. Kurzer concedes that she is not an expert in cognitive function and that she has not conducted any clinical trials involving cognitive function, taught any classes focused on cognitive function, evaluated a person's cognitive function, used the cognitive assessments given to participants in the Madison Memory Study, or been involved in any professional organizations or academic journals that focus on cognitive function. *See Dura*, 285 F.3d at 613 (noting that thoracic surgeon could testify that cancer was too advanced for surgery,

[20] Additionally, the contention that her opinions on impairment, evaluation, or treatment of cognitive function are just "background sections" would not obviate the requirement that she must be qualified in those fields. Fed. R. of Evid. 702.

[21] In their motion, Plaintiffs did not seek to exclude Dr. Kurzer entirely, only her opinions related to cognition and memory, including on whether Prevagen improves memory or provides other cognitive benefits. (Pls. MOL (ECF No. 304) at 25.)

but that offering the critical judgment that radiologist should have discovered cancer sooner would be in purview of an expert in radiology); Pls. MOL (ECF No. 304) at 23-24. Dr. Kurzer also concedes that she does not have expertise in clinical significance, and that she does not know whether the purported cognitive benefits reported in the Madison Memory Study were clinically significant, that is, whether the change affects a person's cognitive function in a meaningful way. *Id.*

Defendants, who bear the burden of establishing the admissibility of Dr. Kurzer's testimony, point to her "decades of experience in conducting and critically evaluating scientific evidence." (Defs. Opp'n. (ECF No. 315) at 28. However, courts have distinguished between different areas of science when evaluating whether a witness is qualified. A scientist who has conducted clinical trials or evaluated scientific evidence in unrelated fields would be unqualified to render opinions involving memory or cognition. For example, in *Trumps v. Toastmaster, Inc.*, 969 F. Supp. 247, 252-53 (S.D.N.Y. 1997), the court found that the witness, a mechanical engineer, was not qualified to express an opinion on electrical engineering because he was unfamiliar with electrical engineering concepts and therefore could not opine on whether the product's electrical design was defective. Furthermore, in *McCullock v. H.B. Fuller Co.*, 981 F.2d 656, 657 (2d Cir. 1992), the Second Circuit affirmed the exclusion of an expert, an engineer, because he did not have experience related to the issue in dispute, which required experience in chemical engineering, toxicology, environmental engineering, or the design of warning labels. Likewise, in *Loyd v. United States*, the court found that although the expert was an internist and infectious disease specialist, he had limited training in neurology, had not treated any patients with the neurological disorder at issue, and admitted that he lacked sufficient expertise, and thus his testimony about the causes of neurological disorders would be conjecture.

No. 08-CIV-9016, 2011 WL 1327043, at *5 (S.D.N.Y. Mar. 31, 2011). *Loyd, Trumps*, and *McCullock* make clear that simply being a doctor or engineer were not enough; rather, these professionals did not have the necessary experience in the specific area of science relevant to the case. *Id.*; *McCullock*, 981 F.2d at 657; *Trumps*, 969 F. Supp. at 252-53.

Because Dr. Kurzer's knowledge and experiences are not in any field closely related to memory and cognition, and she concedes that she is neither an expert in cognitive function nor able to opine on whether the Madison Memory Study's results are clinically significant, any opinions offered by her on memory and cognition would be nothing but speculation and must be excluded.[22] *See In re M/V MSC Flaminia*, 2017 U.S. Dist. LEXIS 119146, at *170 ("If . . . there is a mismatch between the area of expertise and the proffered opinions, there is a possibility of cloaked unreliability. An individual with expertise in one field may not offer opinions in another: the expertise and area of proffered opinions should be closely related."); *Collado v. City of New York*, No. 11-CIV-9041, 2017 WL 4533772, at *7 (S.D.N.Y. Sept. 27, 2017) ("Rule 702 mandates that experts stay within the reasonable confines of their subject area, and cannot render expert opinion on an entirely different field or discipline." (internal quotation marks omitted)).

VIII. DR. KURZER'S ALTERNATIVE ANALYSIS IS NOT USED BY EXPERTS IN THE RELEVANT FIELD, CANNOT BE RECREATED, AND IS UNRELIABLE

Plaintiffs seek to exclude Dr. Kurzer's alternative analysis of the Madison Memory Study as unreliable. (Pls. MOL (ECF No. 304) at 25-27.) First, Defendants attempt to redefine the relevant field, arguing that Dr. Kurzer's alternative analysis of the Madison Memory Study is "utilized by the relevant scientific community, including those in the fields of clinical trials,

[22] Dr. Kurzer's opinions involving memory or cognition are included, for example, in paragraphs 19-35, 48-52 (including Tables 1 and 2), and 60-84 of her report dated April 21, 2021. (Graham Decl. (ECF No. 225) Ex. R, Kurzer Aff. Report.)

statistics, nutrition, and epidemiology." (Defs. Opp'n. (ECF No. 315) at 32.) However, noticeably absent from Defendants' list of fields are memory and cognition, the relevant fields in this matter. As discussed in Section VII above, because she is not qualified as an expert in cognition or memory, Dr. Kurzer cannot opine on whether her analysis, based on logic or common sense, is used by experts in these fields to determine whether Prevagen improves memory or provides other cognitive benefits. (Pls. MOL (ECF No. 304) at 25-27.)

Defendants next contend that Dr. Kurzer's alternative analysis, which looked at whether the test results from the Madison Memory Study trended in any particular directions or were statistically significant, can be recreated by "*any* clinical trial expert, statistician, or even basic scientist for that matter." (Defs. Opp'n. (ECF No. 315) at 28, 32 (emphasis in original).) However, Dr. Kurzer's alternative analysis was not just limited to whether the Madison Memory Study test results were statistically significant or trended in a certain direction. Defendants conveniently ignore a critical aspect of Dr. Kurzer's methodology, one that prevents it from being recreated—how she evaluated the information about trends or statistical significance from the Madison Memory Study to "draw[] conclusions logically" or from her "common sense" that Prevagen improves memory or cognition. (Graham Decl. (ECF No. 225) Ex. R, Kurzer Aff. Report ¶ 48; Matuschak Decl. (ECF No. 305) Ex. D, Kurzer Tr. 204:20–207:25.) For example, although Dr. Kurzer later admitted that mistakes were made in her alternative analysis, resulting in fewer tests "trending" in favor of Prevagen, her conclusion that Prevagen is beneficial remained unchanged. (Pls. MOL (ECF No. 304) at 27.) There are no parameters or principles to indicate, for instance, how many tests were needed to "trend" in favor of Prevagen or how Dr. Kurzer accounted for competing trends favoring placebo in order to reach a conclusion about Prevagen's efficacy. Because Dr. Kurzer's alternative analysis lacks standards, which she

admits, and is based only on her own "logic[]" or "common sense," these opinions are unreliable and must be excluded.[23] (*See id.* at 25-27.)

IX. DEFENDANTS HAVE CONFIRMED THAT DR. GOODMAN SHOULD BE PRECLUDED FROM TESTIFYING ABOUT ANYTHING OTHER THAN HIS ALLERGENICITY STUDY

Defendants' defense of Dr. Goodman's testimony boils down to a series of arguments that are premised on rebutting positions never taken by Plaintiffs or their mechanism of action expert, Dr. Jeremy Berg. Defendants cannot credibly argue that there is *any* link between apoaequorin—the compound at issue in this case—and Dr. Goodman's discussion of other proteins or peptides. These opinions are so far afield of the issues in this case that they would both waste the jury's time and cause confusion. (*See id.* at 30-34.) Because Defendants cannot rebut this argument, they resort to arguing that Dr. Goodman's discussion of other proteins and peptides is appropriate because Plaintiffs took the position that no proteins or peptides could ever have a biological effect. But Defendants cannot cite anywhere that Plaintiffs took that position, or even opined about the bioactivity of proteins or peptides that are not apoaequorin or its derivatives (other than to rebut Defendants' irrelevant opinions). Dr. Goodman's proposed testimony regarding issues unrelated to apoaequorin does not rebut anything, and it should be excluded. Indeed, Defendants concede that Dr. Goodman's proposed testimony does not bear on the mechanism of action or bioactivity of *apoaequorin*. (Defs. Opp'n. (ECF No. 315) at 39-40.) Additionally, because Defendants do not challenge Plaintiffs' argument that Dr. Goodman lacks the expertise to opine regarding apoaequorin's absorption and mechanism of action, his testimony should also be excluded on that basis.

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[23] Dr. Kurzer's unreliable alternative analysis of the Madison Memory Study is in paragraphs 48-53, including Tables 1 and 2, of her report dated April 21, 2021. (Graham Decl. (ECF No. 225) Ex. R, Kurzer Aff. Report.)

A. Dr. Goodman's Only Admissible Testimony Is His Interpretation of His Study of Apoaequorin

Defendants spend most of their discussion of Dr. Goodman's testimony arguing that he should be permitted to testify regarding his own study of apoaequorin. (*Id.* at 32-35.) Plaintiffs did not, however, seek to preclude Dr. Goodman from testifying about his own work.

The parties disagree on the meaning of Dr. Goodman's study of apoaequorin in simulated gastric fluid, and the testimony of both Dr. Goodman and Plaintiffs' expert, Dr. Berg, on this issue is admissible. (*See* Pls. Opp'n. (ECF No. 313) at 30-36, 43-44.) Dr. Berg reviewed Dr. Goodman's work and concluded that it supported Dr. Berg's conclusion that apoaequorin, due to its characteristics, would be rapidly digested into amino acids and possibly some small peptides. (*See* Graham Decl. (ECF No. 308) Ex. I, Berg Aff. Report ¶¶ 25-29; Ex. J, Berg Rebuttal Report ¶¶ 12-15.) Dr. Goodman believes that his study cannot demonstrate anything about how apoaequorin would behave in the human digestive system because the intent of the study was not to simulate digestion. (*See* Matuschak Decl. (ECF No. 305) Ex. F, Goodman Rebuttal Report ¶ 9.) Although Dr. Goodman is wrong, Plaintiffs have not challenged the admissibility of this testimony.

B. Dr. Goodman's Discussion of Other Proteins Should Be Excluded

Dr. Goodman spends the bulk of his expert reports discussing the digestion of compounds that are not apoaequorin. As Plaintiffs noted, Dr. Goodman did not even attempt to determine whether these compounds share characteristics with apoaequorin that would warrant a comparison between the proteins that Dr. Goodman discusses and the protein at issue in this case. (Pls. MOL (ECF No. 304) at 30-33.) Defendants do not, and cannot, refute this point, and it is fatal to the admissibility of Dr. Goodman's testimony on this issue. *See Borsack v. Ford Motor Co.*, No. 04 Civ. 3255 (PAC), 2009 WL 5604383, at *1-3 (S.D.N.Y. Feb. 3, 2009)

(excluding as irrelevant expert testimony regarding mechanism of product that had "substantial differences" with product at issue).

In attempting to gin up the relevance of Dr. Goodman's discussion of proteins that are not apoaequorin, Defendants erroneously claim that Plaintiffs' expert, Dr. Berg, asserted "that an orally administered agent must completely survive the stomach to have a therapeutic effect." (Defs. Opp'n. (ECF No. 315) at 36.) They also inaccurately argue that Dr. Berg opined that "apoaequorin and other proteins must survive the human stomach wholly intact to have a therapeutic effect." (*Id*. at 35.) They further assert that "Dr. Goodman is simply *refuting Plaintiffs'* unsupported assumption that *all* dietary proteins are completely digested." (*Id*. at 39 (emphases in original).) Neither Plaintiffs nor Dr. Berg made *any* of these assertions or assumptions, so Dr. Goodman need not rebut them. Unlike Dr. Goodman, Dr. Berg limited his discussion to apoaequorin.[24]

Specifically, Dr. Berg opined that apoaequorin would be expected to degrade into amino acids and perhaps peptides in the stomach, and to further degrade in the small intestine. (*See* Pls. Opp'n. (ECF No. 313) at 30-31.) Contrary to Defendants' arguments (Defs. Opp'n. (ECF No. 315) at 33-36), Dr. Berg did not base this conclusion solely on Dr. Goodman's work, but also on his own expert background in protein digestion; his review of apoaequorin's biological characteristics; his analysis of apoaequorin using a web-based tool to predict cleavage sites for

[24] Dr. Berg did address proteins other than apoaequorin in his rebuttal report only to respond to Dr. Goodman's discussion of such proteins and explain why one cannot draw conclusions about apoaequorin based on such proteins. Specifically, the proteins cited by Dr. Goodman have different characteristics from apoaequorin that would cause them to perform differently in digestion. (*See, e.g.*, Graham Decl. (ECF No. 308) Ex. J, Berg Rebuttal Report ¶¶ 17, 21-22.) Dr. Berg would not offer such testimony if Dr. Goodman's irrelevant testimony were properly excluded.

apoaequorin; and his review of Defendants' rat and dog studies. (*See* Graham Decl. (ECF No. 308) Ex. I, Berg Aff. Report ¶¶ 15-46; Ex. J, Berg Rebuttal Report ¶¶ 5-22.) Plaintiffs do not object to Dr. Goodman disagreeing with Plaintiffs' interpretation of his own study of apoaequorin, but they do object to Dr. Goodman introducing irrelevant "evidence" about other compounds to challenge Dr. Berg's conclusions about apoaequorin.

Defendants argue that Dr. Goodman's testimony recites "well-known principles of the human digestion process" in rebuttal to Dr. Berg's analysis. (Defs. Opp'n. (ECF No. 315) at 33.) Yet Defendants fail to point to any "well-known principles of the human digestion process" that Dr. Goodman cited in specific rebuttal to Dr. Berg's conclusions about apoaequorin. Instead, they erroneously argue that Dr. Berg took the position that "apoaequorin and other proteins *must* survive the human stomach wholly intact to have a therapeutic effect." (*Id*. at 35 (emphasis in original).) They have no citation for Dr. Berg taking this position because there isn't one.[25]

Defendants' brief is otherwise littered with mischaracterizations of Plaintiffs' positions, apparently intended to obscure the fact that they have no substantive response to Plaintiffs' arguments.[26] For example, Defendants assert that Plaintiffs "acknowledge[ed] proteins found in

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[25] It is unclear why Defendants are trying to relitigate their *Daubert* motion in their opposition to Plaintiffs' *Daubert* motion, but they spend considerable time discussing why they, and Dr. Goodman, disagree with Dr. Berg. (Defs. Opp'n. (ECF No. 315) at 33-36.) In doing so, they incorrectly assert that Dr. Berg's opinion should be discounted because he did not conduct his own apoaequorin studies. (*See id*. at 34, 37.) Dr. Berg is qualified to talk about the science and available evidence related to apoaequorin and need not have conducted his own laboratory research in order to opine on these issues. In order to present conclusions regarding the *absence* of evidence, Dr. Berg needed only to review *all available evidence*—which he did. (*See* Pls. Opp'n. (ECF No. 313) at 32-33.) For the reasons outlined in Plaintiffs' Opposition to Defendants' *Daubert* motion, Dr. Berg should be permitted to offer his well-supported opinions. (*Id*. at 30-44.)

[26] Defendants also attempt to distinguish the cases cited by Plaintiffs based on their facts, but those cases unquestionably stand for the *Daubert* principles for which they are cited. *Compare* Defs. Opp'n. (ECF No. 315) at 37-39 *with* Pls. MOL (ECF No. 304) at 31-33.)

breast milk are not always allergens" (*Id.* at 37 (citing Pls. Opp'n. (ECF No. 313) at 32)), but Plaintiffs never said that. More importantly, Defendants have not pointed to any proteins found in breast milk that are not allergens. And even more importantly than that, Defendants have not explained why proteins in breast milk—allergenic or not—have any relevance to a case about memory or cognition or any similarities to the relevant compound, apoaequorin. (*See also* Pls. MOL (ECF No. 304) at 32-33.)

As another example, Defendants state that "Plaintiffs cite *no support* for their *bald assertion* that potential differences in allergenic and non-allergenic proteins render any portions of Dr. Goodman's testimony concerning protein digestion unreliable." (Defs. Opp'n. (ECF No. 315) at 37 (emphases added).) They fail to substantively address Plaintiffs' points on this issue, including that the digestion characteristics of allergenic and non-allergenic dietary proteins differ and that Dr. Goodman conceded this fact. (*See* Pls. MOL (ECF No. 304) at 30-33.)

In the end, the only way in which Defendants attempt to refute Plaintiffs' arguments is by mischaracterizing Plaintiffs' positions and Dr. Berg's expert opinions. Defendants have failed to show how Dr. Goodman's discussion of other proteins is at all relevant to apoaequorin. Because there is a gap between Dr. Goodman's analysis of other proteins and the protein at issue in this case, and Defendants have failed to bridge that gap, the testimony should be excluded. *See GE v. Joiner*, 522 U.S. 136, 146 (1997).

C. Dr. Goodman Should Be Precluded From Testifying About the Absorption or Bioactivity of Apoaequorin, or About Other Potential Mechanisms of Action

Defendants argue that Plaintiffs seek to preclude Dr. Goodman's discussion of "potential absorption bioactivity or mechanism of action for apoaequorin or byproducts that may result during the human digestion process" on the basis that it would supposedly hurt Plaintiffs' case. (Defs. Opp'n. (ECF No. 315) at 33.) The actual bases for excluding this testimony, which

Defendants do not address, can be found in Plaintiffs' opening Memorandum. (Pls. MOL (ECF No. 304) at 33-34 (discussing speculative nature of the testimony and Dr. Goodman's lack of expertise).) In any event, Defendants concede that "Dr. Goodman is not testifying about the absorption, bioactivity, or mechanism of action *of apoaequorin*." (Defs. Opp'n. (ECF No. 315) at 33 (emphasis in original).) This concession, that Dr. Goodman is not proposing to testify about the compound at issue in this case, provides an additional reason to exclude Dr. Goodman's testimony.

Notably, Defendants also do not challenge Plaintiffs' argument that Dr. Goodman lacks the expertise to opine on the potential absorption or bioactivity of apoaequorin. (*See* Pls. MOL (ECF No. 304) at 33.) They do not challenge Plaintiffs' arguments that Dr. Goodman is not an expert on protein absorption outside the context of allergens and celiac peptides; not an expert on biochemistry as it relates to "how each protein is folded or produced or what it will do"; and not an expert on potential therapeutic or bioactive effects of apoaequorin. (*See id.* at 33.) Dr. Goodman's testimony about topics other than his apoaequorin studies should also be excluded on this basis.[27]

[27] By contrast, Defendants' assertions that Dr. Berg lacks expertise ring hollow. They state, without citation, that Dr. Berg "admittedly is not an expert in either allergy or digestion." (Defs. Opp'n. (ECF No. 315) at 37.) For the first point, Defendants cite nothing, nor do they explain how expertise in allergy is relevant to any issue in this case. For the second point, Dr. Berg made clear that he is an expert on the aspects of digestion that are relevant to this case. (*See* Pls. Opp'n. (ECF No. 313) at 34-35.) Indeed, he wrote a leading textbook that addresses such issues. (*See id.* at 34.)

X. DEFENDANTS HAVE FAILED TO SUPPORT THE ADMISSIBILITY OF DR. GORTLER'S TESTIMONY

A. Dr. Gortler Should Be Precluded from Testifying About FDA Requirements for Dietary Supplements

Plaintiffs seek to exclude Dr. Gortler's testimony about FDA requirements for dietary supplements as irrelevant. (*Id.* at 36-37.) Although they cite to nothing in Dr. Berg's report or testimony, Defendants attempt to rebut this argument by asserting that Dr. Berg took a position he actually did not take: "that Prevagen and Apoaequorin Need a Known Mechanism of Action to Prove Therapeutic Effect." (Defs. Opp'n. (ECF No. 315) at 40.) Dr. Gortler's proposed testimony is improper rebuttal. It should also be excluded as irrelevant. (*See* Pls. MOL (ECF No. 304) at 10-12, 36-37.)[28]

B. Dr. Gortler's Discussion of Other Drugs That Work, and Unsupported Speculation That Apoaequorin Might Work, Should Be Excluded

Dr. Gortler's proposed testimony on drugs and substances other than apoaequorin that might have an effect on the body should be excluded as irrelevant, confusing, prejudicial, and a waste of the jury's time. (*Id.* at 35-36.) Dr. Gortler proposes to testify about a multitude of ways in which drugs might work. Defendants concede that none of this testimony is tied to Prevagen or apoaequorin but argue that Dr. Gortler's testimony is relevant "to highlight the possibility that Prevagen and apoaequorin could be similarly effective." (Defs. Opp'n. (ECF No. 315) at 42.) Yet, Dr. Gortler failed to determine whether any of these drugs or mechanisms of action have any similarities, or relevance, to Prevagen or apoaequorin (*see* Pls. MOL (ECF No. 304) at 35-36). If Dr. Gortler's testimony were admissible here, it would be admissible in *any* case about

[28] Plaintiffs' argument regarding Dr. Gortler's proposed FDA testimony incorporated their discussion of the relevance of FDA regulations in general, which appeared earlier in Plaintiffs' opening Memorandum. (*See* Pls. MOL (ECF No. 304) at 36.) Plaintiffs inadvertently referenced Section III.A. of their brief, but intended to reference Section III.B, which appears at pages 10-12.

whether *any* substance has a therapeutic effect of *any* kind. His proposed testimony is a textbook example of the need for this court to exercise its gatekeeping function. *See Amorgianos*, 303 F.3d at 265 (the trial court is "charged with 'the task of ensuring that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand'") (quoting *Daubert*, 509 U.S. at 597); s*ee also McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1244-46 (11th Cir. 2005) (rejecting expert's analogy between a dietary supplement and a drug for failing to show the reliability of each step of his analysis); *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 278-79 (5th Cir. 1998) (affirming exclusion of expert testimony where expert drew conclusions about the effect of one chemical based on the effect of another chemical without attempting to draw similarities between the two chemicals); *Sparling v. Doyle*, No. EP-13-CV-323-DCG, 2015 U.S. Dist. LEXIS 97204, at *57-58 (W.D. Tex. July 27, 2015) (excluding expert testimony where expert drew conclusions about the effects of one drug based on other drugs "without accounting for any of the differences"). Expert testimony that is essentially an apples and oranges comparison, or about products that are substantially different from the product at issue, should be excluded. (*See* Pls. MOL at 35-36 (and cases cited therein).)[29]

C. Dr. Gortler's Discussion of Alzheimer's Disease and Calcium-Binding Should Be Excluded

Dr. Gortler's discussion of calcium-binding and Alzheimer's disease should be excluded because it is unreliable and has no bearing on any issue in this case. (*See* Pls. MOL (ECF No. 304) at 37-38.) Defendants do not dispute that apoaequorin must be present in the brain to have a calcium-binding effect on brain cells. (S*ee* Pls. MOL (ECF No. 304) at 37-38.) They also do not dispute that they admitted that apoaequorin is hydrolyzed into amino acids when orally

[29] Defendants' only argument against the cases cited by Plaintiffs in their opening Memorandum is that they did not involve rebuttal testimony. (Defs. Opp'n. (ECF No. 315) at 42 n.15.) Whether the testimony is affirmative or in rebuttal is irrelevant to the point.

consumed. (*See id*.) They also do not dispute that their experts expressed skepticism about apoaequorin's ability to enter the bloodstream and cross the blood-brain barrier. (C*ompare id*. at 38-39 w*ith* Defs. Opp'n. (ECF No. 315) at 43-44).) Yet even though Defendants have conceded that apoaequorin likely cannot get into the brain, they attempt to persuade the Court that Dr. Gortler's Alzheimer's disease opinion is relevant by arguing that they did not abandon their original theory that apoaequorin worked by crossing the blood-brain barrier. (*Id.* at 43.) Defendants make this argument even though, in the same brief, they characterize as "outdated" and "frankly, wrong" the position that "apoaequorin must cross the human blood-brain barrier in order to have a beneficial effect on cognition." (*Id.* at 4.)

The lack of relevance or reliability of Dr. Gortler's calcium-binding discussion is further demonstrated by Dr. Gortler's reliance on a rat study to support the notion that apoaequorin can have a positive effect on human brain cells. In the study upon which Dr. Gortler relies, apoaequorin was injected directly into rats' brains—yet Dr. Gortler failed to explain how this study demonstrates that orally-consumed apoaequorin can have an effect on human brains. (*See* Pls. MOL (ECF No. 304) at 38-39.) Defendants do not explain how that jump in logic is justified. Instead, they argue that Dr. Gortler rebuts an "extreme position" that Dr. Berg never took—that "there is no *possible* way for Prevagen or apoaequorin to have a therapeutic effect on humans." (Defs. Opp'n. (ECF No. 315) at 44 (emphasis in original).) First, the rat study does not rebut this "extreme position." Second, once again, Dr. Berg never took that position. Dr. Berg's position, instead, is that he has "not seen any evidence, in the scientific literature or otherwise, that the active ingredient in Prevagen—apoaequorin—could have any therapeutic effect on the human body through any reasonable mechanism of action." (Graham Decl. (ECF No. 308) Ex. J, Berg Rebuttal Report ¶ 2.)

Defendants have presented no evidence or argument to support their conclusion that calcium-binding is a "*possible* mechanism of action for apoaequorin." (Defs. Opp'n. (ECF No. 315) at 43 (emphasis in original).) To allow Dr. Gortler to testify about calcium-related theories related to Alzheimer's disease would lead the jury to make unwarranted associations between such theories and the unsupported theory that apoaequorin could reach the brain and bind calcium. Such testimony has no place in a courtroom.

D. Dr. Gortler's "Active Transport" Testimony Should Be Excluded as Unreliable

Dr. Gortler's speculation about consuming apoaequorin together with dietary cholesterol should be excluded because he does not possess the knowledge or expertise to testify about that theory. (*See* Pls. MOL (ECF No. 304) at 39-41.) Defendants decline to rebut Plaintiffs' argument that Dr. Gortler's testimony on this issue is woefully unreliable. They do not challenge the facts that Dr. Gortler did not understand the literature he cited for this theory; that he did not conduct the analysis in question and could not explain it; that he could not answer specific, basic questions about a figure he copied into his report; and that he could not explain or answer basic questions about the methodology used in the literature he cites. (*See id.* at 39-40.) Rather than assert that Dr. Gortler can understand and explain these things, Defendants argue that Dr. Gortler has expertise as a pharmacologist and pharmacist. (Defs. Opp'n. (ECF No. 315) at 44.) This ignores that Dr. Gortler confirmed that he is *not* an expert in the scientific methodology used in the references he cites. (*See* Pls. MOL (ECF No. 304) at 40.)

Tellingly, Defendants argue that "*most importantly*, [Dr. Gortler] is testifying simply to the *conclusions rendered* in the studies he cites." (Defs. Opp'n. (ECF No. 315) at 44 (first emphasis added).) They have therefore confirmed they intend to use Dr. Gortler not as an expert, but as a vehicle for hearsay. (*See* Pls. MOL (ECF No. 304) at 40-41 (and cases cited

therein).) This renders Dr. Gortler's proposed testimony on this subject inadmissible. Because Dr. Gortler could not answer those questions about the cited references or explain the methodology, his conclusions are unreliable. "Hearsay is normally not permitted into evidence because the absence of an opportunity to cross-examine the source of the hearsay information renders it unreliable." *Feltman v. Culmin Staffing Grp., Inc.*, 603 B.R. 888, 894 (S.D.N.Y. 2019) (excluding expert testimony where expert relied on data from an article written by others but did not exercise independent diligence as to the reasonableness of that data or its applicability to the case) (quoting *TK-7 Corp. v. Estate of Barbouti*, 993 F.2d 722, 732-33 (10th Cir. 1993)).

Medisim Ltd. v. BestMed, LLC, cited by Defendants, demonstrates why Dr. Gortler's failure to understand his own references renders his opinion inadmissible here. 861 F. Supp. 2d 158 (S.D.N.Y. 2012) (cited in Defs. Opp'n. (ECF No. 315) at 45). In that case, the court concluded that an expert's testimony, which was premised in part on another expert's report, was admissible because the expert—unlike Dr. Gortler here—had done the requisite work and analysis to justify his reliance on the other expert's report:

> Where a testifying expert has expertise in the field covered by a consulting expert *and independently verifies the latter's conclusions*, there is no danger that the former is acting as a mere "mouthpiece or conduit" of the latter. [The testifying expert] is qualified to analyze source code; *in fact, he reviewed the same source code documents as [the consulting expert]*. Furthermore, the context in which [the testifying expert] refers to [the consulting expert's report] makes clear that he does so only after analyzing the source code on his own. That he reached the same conclusions as [the consulting expert] does not mean that he "parrots [the consulting expert's] opinion without adding any analysis."

861 F. Supp. 2d at 169 (emphases added) (quoting plaintiff's *Daubert* brief). Here, by contrast, Dr. Gortler conceded that he had no expertise in the methodology used in the references he cites. (*See* Pls. MOL (ECF No. 304) at 40.) Unlike the expert in *Medisim*, Dr. Gortler was incapable

of independently verifying the conclusions reached in those references. Indeed, Dr. Gortler could not even explain the analysis that led to the conclusions he parroted in his report. (*See id.* at 39-41.) His testimony should be excluded.

E. Dr. Gortler's Testimony Regarding the Madison Memory Study Should Be Excluded

Defendants do not dispute the reasons Plaintiffs cited as the bases for excluding Dr. Gortler's testimony regarding the Madison Memory Study—that he did not have an opinion on it; did not intend to offer an opinion on it; and simply "parroted some sections of the study itself" in his expert report. (*See id.* at 41.) Instead, Defendants offer an additional reason to exclude his testimony—that it is not offered in rebuttal to anything. Defendants argue that Dr. Gortler's testimony regarding the Madison Memory Study is intended to rebut "Dr. Berg's Testimony that Prevagen and Apoaequorin Have No Therapeutic Effect." (Defs. Opp'n. (ECF No. 315) at 45.) But once again, this is not an opinion offered by Dr. Berg. Dr. Berg did not opine on the Madison Memory Study at all. He simply concluded, based on *biological* expertise and evidence, that there is no such evidence that Prevagen could have a therapeutic effect. (*See* Pls. MOL (ECF No. 304) at 31-34.)

F. Dr. Gortler Should Be Precluded From Testifying That Prevagen Is Safe

Defendants do not dispute the primary reason Dr. Gortler should be precluded from testifying that Prevagen is safe—that this opinion is not relevant to any issue in the case and has nothing to do with substantiation of advertising claims. (*See id.* at 41-42.) That fact alone is determinative on this issue.

Instead, Defendants erroneously contend that Dr. Gortler's testimony regarding safety rebuts testimony by Dr. Berg "criticizing Quincy's statements to the FDA claiming that Prevagen should be '[g]enerally recognized as safe.'" (Defs. Opp'n. (ECF No. 315) at 45 (citing Graham

Decl. (ECF No. 308) Ex. I, Berg Aff. Report ¶ 29).) However, Dr. Berg was neither criticizing Defendants' statements to the FDA nor opining regarding safety.[30] Rather, he was noting that Defendants told the FDA that, "following oral consumption by humans, Apoaequorin is likely to be completely hydrolyzed to individual amino acids that will be absorbed in a process similar to other dietary proteins." (Graham Decl. (ECF No. 308) Ex. I, Berg Aff. Report ¶ 29 (quoting Defendants' 2014 FDA Submission).) Dr. Berg was not opining regarding the safety of apoaequorin at all, but rather citing Defendants' agreement with his conclusion that apoaequorin is likely degraded into amino acids during digestion. (*See id.* ¶ 29.) Therefore, Dr. Gortler should be precluded from testifying that Prevagen is safe.[31]

XI. DRS. KURZER, SCHWARTZ, AND KATZ SHOULD BE PRECLUDED FROM TESTIFYING REGARDING PREVAGEN'S POTENTIAL MECHANISMS OF ACTION

Defendants attempt to make the mechanism of action testimony of Drs. Kurzer, Schwartz, and Katz relevant by arguing that Plaintiffs took positions they never took. For example, they state it is "Plaintiffs' position that there is no evidence that apoaequorin has a fully known mechanism of action therefore it has no therapeutic effect." (Defs. Opp'n. (ECF No. 315) at 46.) This position is not in the cited portion of Plaintiffs' Complaint, nor does it appear anywhere else. This is with good reason – the parties are *in agreement* that a mechanism of

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[30] The statements Dr. Berg relied upon appeared in Defendants' "Generally Regarded as Safe" submissions to the FDA. "GRAS" refers to a procedure under which companies such as Defendants can sell a food substance without FDA approval if they submit a qualified expert opinion that the product is generally recognized as safe under the conditions of its intended use. *See* www.fda.gov/food/generally-recognized-safe-gras/about-gras-notification-program (visited Oct. 5, 2022). Although the statements were included in a GRAS submission, they were not cited by Dr. Berg for any conclusions related to safety. (*See* Graham Decl. (ECF No. 308) Ex. I, Berg Aff. Report ¶ 29.)

[31] For the same reasons, Drs. Kurzer, Schwartz, and Katz should be precluded from testifying that Prevagen is safe. (*See* Pls. MOL (ECF No. 304) at 41 n.7.)

action need not be known in order for a compound to have a therapeutic effect. Defendants cannot make their experts' proposed testimony relevant by inventing a dispute.

Even if this proposed testimony were relevant, Defendants fail to counter Plaintiffs' arguments why the proposed testimony is unreliable and prejudicial. Specifically, they assert, without explanation, that each of these experts offers "plausible" mechanisms of action for Prevagen. (*Id.* at 46.) It may well be that the articulated mechanisms of action are plausible for some drugs, but Defendants have failed to articulate why these mechanisms of action are plausible *for Prevagen*. The testimony should be excluded.

A. Dr. Kurzer's Proposed Mechanism of Action Testimony is Unreliable, Irrelevant, and Prejudicial

Plaintiffs argue that Dr. Kurzer does not link her mechanism of action theories to Prevagen or apoaequorin, and Defendants do not challenge that fact. (*See* Pls. MOL (ECF No. 304) at 43.)[32] Instead of arguing that Dr. Kurzer's testimony is relevant and reliable, Defendants merely argue that Dr. Kurzer's testimony is intended to rebut Plaintiffs' Complaint allegations. Yet Defendants have not actually cited Complaint allegations that Dr. Kurzer allegedly rebutted.

The first purported Complaint allegation that Defendants cite is that "'apoaequorin is rapidly digested in the stomach and broken down into amino acids like any other dietary protein' and accordingly 'cannot cross the human blood brain barrier or enter the human brain.'" (Defs. Opp'n. (ECF No. 315) at 47 (purporting to quote Compl. (ECF No. 1) ¶ 31).) The first part of the quote is incomplete—the Complaint states that "*Defendants' safety studies show that*

[32] Defendants attempt to distinguish *Mancuso v. Consolidated Edison Co.*, 967 F. Supp. 1437, 1441 (S.D.N.Y. 1997), arguing that it "focuses on affirmative expert testimony, not *rebuttal* testimony, and is inapplicable here." (Defs. Opp'n. (ECF No. 315) at 47 n.16.) This argument is misplaced in part because Dr. Kurzer never submitted any rebuttal testimony. But more importantly, the proposition for which Plaintiffs cited it—that expert testimony should be excluded if it is speculative or conjectural—applies equally to affirmative and rebuttal testimony. (*See* Pls. MOL (ECF No. 304) at 43.)

apoaequorin is rapidly digested in the stomach and broken down into amino acids and small peptides like any other protein." (Compl. (ECF No. 1) ¶ 31 (emphasis added).) The second part of the quote does not actually come from the Complaint—it comes from Dr. Kurzer's report, which mischaracterizes what the Complaint said. (*See* Graham Decl. (ECF No. 225) Ex. R, Kurzer Report ¶ 56 (contending that Plaintiffs' position is that apoaequorin "cannot cross the human blood brain barrier or enter the human brain").) The Complaint actually said, "Defendants . . . do not have studies showing that orally-administered apoaequorin can cross the human blood-brain barrier and therefore do not have *evidence* that apoaequorin enters the brain." (Compl. (ECF No. 1) ¶ 31 (emphasis added).)

Defendants also inexplicably argue that Dr. Kurzer's mechanism of action testimony is in response to Plaintiffs' Complaint allegation that "the absorption of AQ/Prevagen is *not yet fully understood* and therefore the exact mechanism by which AQ influences cognitive function is *not known at this time*." (Defs. Opp'n. (ECF No. 315) at 47 (emphases added by Defendants) (purporting to cite Compl. (ECF No. 1) ¶ 56).) Yet that quote does not appear anywhere in Plaintiffs' Complaint. It is instead a quote from Dr. Kurzer's own report. (Graham Decl. (ECF No. 225) Ex. R, Kurzer Report ¶ 56.) Dr. Kurzer, obviously, cannot be permitted to rebut herself. Dr. Kurzer's opinion is inadmissible because it professes to rebut positions that were never taken by Plaintiffs. The statement that "the absorption of AQ/Prevagen is not yet fully understood" assumes that apoaequorin and/or Prevagen is absorbed but that we do not know how. Plaintiffs agree that there is no known mechanism of action for Prevagen—and Dr. Kurzer's testimony is not needed to establish that fact. But Plaintiffs have never assumed that orally administered apoaequorin is absorbed. Dr. Kurzer's testimony should therefore be excluded as irrelevant, speculative and unreliable, and prejudicial.

B. Dr. Schwartz's Proposed Mechanism of Action Testimony Should Be Excluded as Unreliable, Irrelevant, and Prejudicial

Defendants argue that Dr. Schwartz identifies plausible mechanisms of action for other substances but concede that Dr. Schwartz has not identified plausible mechanisms of action specific to apoaequorin. (Defs. Opp'n. (ECF No. 315) at 48.)[33] Instead, they once again argue that their expert is rebutting things that Plaintiffs never said. (S*ee id*. at 47 (describing "Plaintiffs' allegations that Prevagen cannot work because its mechanism of action is unknown").) And once again, Defendants attempt to assign their own experts' statements to Plaintiffs. They state, "Dr. Schwartz agrees with Plaintiffs that Prevagen's mechanism of action is 'not completely understood.'" (*Id*. at 47.) Yet it is Dr. Schwartz—not Plaintiffs—who opined that "Prevagen's precise mechanism of action is not completely understood." (Graham Decl. (ECF No. 225) Ex. W, Schwartz Aff. Report ¶ 13.) Dr. Schwartz's statement assumes Prevagen works, but that how it works is not known. Plaintiffs have never made that assumption.

Defendants next argue that Dr. Schwartz's irrelevant discussion of mechanisms and compounds that are not Prevagen or apoaequorin, without determining whether they share any characteristics with Prevagen or apoaequorin, should be admitted for the proposition that a mechanism of action need not be known for a compound to have clinical benefits. (Defs. Opp'n. (ECF No. 315) at 47-48.) This issue is not in dispute in this case, and it is certainly not a reason to permit speculative, irrelevant, and prejudicial testimony. Defendants fail to explain how

[33] Dr. Schwartz did echo Defendants' old calcium-binding theory with respect to apoaequorin. For the reasons stated in Plaintiffs' opening Memorandum (*see* Pls. MOL (ECF No. 304) at 44) and at *supra* Section X.C., Dr. Schwartz should be prohibited from opining on this theory. In any event, Defendants do not appear to oppose Plaintiffs' argument that he should be precluded from testifying as to this theory. (*See* Defs. Opp'n. (ECF No. 315) at 47-49.)

testimony regarding substances other than apoaequorin regarding a point that is not in dispute would be helpful to the jury. (*See id*. at 48-49.)[34]

C. Dr. Katz's Proposed Mechanism of Action Testimony Should Be Excluded as Unreliable, Irrelevant, and Prejudicial

Dr. Katz's proposed mechanism of action testimony should be excluded because (a) his discussion of the calcium-binding theory is speculative; (b) his discussion of the gut-brain axis theory is not tied to apoaequorin in any way; and (c) his discussion of substances other than apoaequorin is not tied to apoaequorin in any way. (S*ee* Pls. MOL (ECF No. 304) at 45-46.) Defendants do not dispute these points. Instead, once again, they quote their expert, and not Plaintiffs, in stating that Plaintiffs took the position that "[b]ecause apoaequorin does not cross the blood brain barrier in humans, there is no plausible mechanism of action." (*See* Defs. Opp'n. (ECF No. 315) at 49 (quoting Graham Decl. (ECF No. 225) Ex. O, Katz Aff. Report ¶ 50).) In any event, testimony regarding other mechanisms and other substances does not rebut the point that there is no plausible mechanism of action for *Prevagen*. The testimony should be excluded.

[34] Defendants also cite Dr. Schwartz's legal speculation that "mechanism of action is not a critical feature of substantiating the benefits of a dietary supplement." (Defs. Opp'n. (ECF No. 315) at 48.) For the reasons set forth in Section II.A. above, this testimony should be excluded.

XII. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court grant their motion to exclude certain testimony of Drs. David Schwartz, David Katz, Lee-Jen Wei, Mindy Kurzer, Richard Goodman, and David Gortler.

Dated: October 21, 2022

Respectfully submitted,

FEDERAL TRADE COMMISSION

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CERTIFICATE OF SERVICE

I certify that on this 21st day of October 2022, I caused service of the foregoing Plaintiffs' Reply in support of their Motion to Exclude the Testimony of Drs. David Schwartz, David Katz, Lee-Jen Wei, Mindy Kurzer, Richard Goodman, and David Gortler to be made by electronic filing with the Clerk of the Court using the CM/ECF system, which will send a Notice of Electronic Filing to all counsel of record.

Dated: October 21, 2022

/s/ Annette Soberats
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